February 14, 2013

Alexion Reports Fourth Quarter and Full Year 2012 Results

- Soliris® (eculizumab) Net Product Sales Increased 45 Percent to $1.134 Billion in 2012 -

- Continued Steady Growth of Soliris in PNH —

- aHUS Launch Progresses with Increasing Number of New Patients Starting on Soliris —

- Pipeline Advances with Five Therapeutic Candidates Targeting Severe and Ultra-Rare Disorders -

Fourth Quarter 2012 Financial Highlights:

- Q4 2012 net product sales increased 41 percent to $320.5 million, compared to $227.6 million in Q4 2011.
- Q4 2012 GAAP net income increased 68 percent to $81.0 million, or $0.40 per share, compared to Q4 2011 GAAP net income of $48.2 million, or $0.25 per share.
- Q4 2012 non-GAAP net income increased 52 percent to $122.3 million, or $0.60 per share, compared to Q4 2011 non-GAAP net income of $80.5 million, or $0.41 per share.

Full-Year 2012 Financial Highlights:

- 2012 net product sales increased 45 percent to $1.134 billion, compared to $783.4 million in 2011.
- 2012 GAAP net income increased 45 percent to $254.8 million, or $1.28 per share, compared to 2011 GAAP net income of $175.3 million, or $0.91 per share.
- 2012 non-GAAP net income increased 60 percent to $425.2 million, or $2.13 per share, compared to 2011 non-GAAP net income of $266.1 million, or $1.38 per share.

CHESHIRE, Conn.--(BUSINESS WIRE)-- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced financial results for the quarter and year ended December 31, 2012. For the three months ended December 31, 2012, Alexion Pharmaceuticals, Inc. ("Alexion" or the "Company") reported net product sales of Soliris® (eculizumab) of $320.5 million, compared to $227.6 million for the same period in 2011. The year-on-year increase in net product sales of 41 percent reflected steady additions of new patients with paroxysmal nocturnal hemoglobinuria (PNH) globally, and an increasing number of new patients with atypical Hemolytic Uremic Syndrome (aHUS) commencing Soliris treatment.

Soliris is approved for patients with PNH in the US, European Union, Japan and other territories as the first and only treatment indicated for this ultra-rare, debilitating and life-threatening blood disease. Soliris is also approved for patients with aHUS in the US and European Union as the first and only treatment indicated for this ultra-rare, life-threatening, genetic disease.

Alexion's non-GAAP operating results are equal to GAAP operating results adjusted for the impact of share-based compensation expense, acquisition-related costs, taxes related to acquisition structuring, intellectual property settlements, intangible asset impairments and non-cash taxes. A full reconciliation of non-GAAP results is included later in this press release.

Fourth Quarter Non-GAAP Financial Results:

The Company reported non-GAAP net income of $122.3 million, or $0.60 per share in Q4 2012, compared to non-GAAP net income of $80.5 million, or $0.41 per share, in Q4 2011.

Alexion's non-GAAP operating expenses for Q4 2012 were $163.2 million, compared to $111.2 million for Q4 2011. Non-GAAP research and development (R&D) expenses for Q4 2012 were $59.9 million, compared to $32.1 million for Q4 2011. Non-GAAP selling, general and administrative (SG&A) expenses for Q4 2012 were $103.3 million, compared to $79.1 million for Q4 2011.

Fourth Quarter GAAP Financial Results:

Alexion reported GAAP net income of $81.0 million, or $0.40 per share in Q4 2012, compared to Q4 2011 GAAP net income of $48.2 million, or $0.25 per share.

On a GAAP basis, operating expenses for Q4 2012 were $179.5 million, compared to $123.4 million for Q4 2011. GAAP R&D expenses for Q4 2012 were $63.4 million, compared to $34.4 million for Q4 2011. GAAP SG&A expenses for Q4 2012 were $112.6 million, compared to $86.6 million for Q4 2011. Acquisition-related costs for Q4 2012 were $3.4 million, compared to $2.3 million for Q4 2011.

Full Year 2012 Non-GAAP Financial Results:

The Company reported non-GAAP net income of $425.2 million in 2012, or $2.13 per share, compared to non-GAAP net income of $266.1 million, or $1.38 per share, in 2011.

Alexion's non-GAAP operating expenses for the full year 2012 were $556.2 million, compared to $403.2 million for 2011. Non-GAAP R&D expenses for 2012 were $208.9 million, compared to $127.7 million for the prior year. Non-GAAP SG&A expenses for 2012 were $347.3 million, compared to $275.5 million in 2011.

Full Year 2012 GAAP Financial Results:

Alexion reported GAAP net income of $254.8 million, or $1.28 per share, in 2012 compared to 2011 GAAP net income of $175.3 million, or $0.91 per share.

Alexion's GAAP operating expenses for the full year 2012 were $656.9 million, compared to $459.5 million for the prior year. GAAP R&D expenses for 2012 were $222.7 million, compared to $137.4 million in 2011. GAAP SG&A expenses for 2012 were $384.7 million, compared to $308.2 million for the prior year. Acquisition-related costs for 2012 were $22.8 million, compared to $13.5 million for 2011. In Q3 2012, the Company also recorded an intangible asset impairment of $26.3 million.

Balance Sheet:

As of December 31, 2012, the Company had $989.5 million in cash and cash equivalents compared to $540.9 million at December 31, 2011.

"In 2012, we continued to expand the global presence of our PNH operations as we also commenced our activities to transform the lives of patients suffering with aHUS," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "Throughout 2013, we will focus on serving more patients with PNH and aHUS globally, and at the same time, we will advance our nine lead development programs in severe and ultra-rare disorders with Soliris and four additional highly innovative therapeutics."

Research and Development Progress:

Alexion currently has development programs underway with its five highly innovative therapeutic candidates: eculizumab (Soliris) and four additional novel therapeutic candidates beyond eculizumab that have the potential to become first-in-class therapies for patients with other severe and ultra-rare disorders.

Ultra-Rare Disease Programs With Eculizumab

- **Nephrology- STEC-HUS:** Data from the full cohort of 198 enrolled patients in the Company-sponsored Shiga-toxin-producing *E. coli* hemolytic uremic syndrome (STEC-HUS) trial were presented at the American Society of Nephrology (ASN) meeting. Preliminary findings from an exploratory post hoc, matched-control analysis of patients with severe STEC-HUS receiving eculizumab versus other patients who received only best supportive care during the German epidemic were also reported at ASN.
- **Nephrology- Kidney Transplant:** Eculizumab is now being evaluated in two different potential kidney transplant indications. Enrollment is ongoing in Company-sponsored, multi-national, living-donor and deceased-donor kidney transplant trials in patients at elevated risk of Acute Humoral Rejection (AHR), also known as antibody mediated rejection. Alexion is also expanding its kidney transplant program to include a delayed-graft function (DGF) clinical trial.
- **Neurology- NMO:** The Company has commenced discussions with regulators in both the United States and Europe to discuss plans for a Company-sponsored multi-national, placebo-controlled, registration trial in relapsing neuromyelitis optica (NMO).
- **Neurology- MG:** Alexion continues to work with investigators to design the next clinical trial to evaluate eculizumab as a treatment for patients with severe myasthenia gravis (MG).

Ultra-Rare Disease Programs With Highly Innovative Therapeutic Candidates Beyond Eculizumab

- **Asfotase Alfa:** A natural history study is ongoing in infants with hypophosphatasia (HPP), an ultra-rare, inherited and life-threatening metabolic disease. The Company is also completing optimization of the manufacturing process for asfotase

alfa.

- **cPMP Replacement Therapy:** Alexion is developing a cPMP replacement therapy for the treatment of patients with Molybdenum Cofactor Deficiency Type A, a severe, ultra-rare and genetic metabolic disorder that is fatal in newborns. The Company continues to accelerate the regulatory and manufacturing processes for this therapeutic candidate and expects to initiate clinical studies in mid-2013.
- **ALXN1102/ALXN1103:** Enrollment continues in a Phase I study to characterize the mechanism of action and develop initial safety data for ALXN1102 and ALXN1103, intravenous and sub-cutaneous versions, respectively, of one of Alexion's novel complement inhibitors.
- **ALXN1007:** The Company has completed dosing in a Phase I study of ALXN1007, a novel anti-inflammatory antibody, to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of this therapeutic candidate in healthy volunteers.

2013 Financial Guidance:

In 2013, worldwide net product sales are expected to be within a range of $1.490 to $1.505 billion. On a non-GAAP basis, R&D expenses are expected to be in the range of $285 to $295 million, and SG&A expenses in the range of $425 to $435 million. Cost of sales is expected to be approximately 10 percent of net product sales. The non-GAAP effective tax rate, reported on a cash tax liability basis, is expected to be in the range of 7 to 9 percent. Based on a forecast of approximately 205 million diluted shares outstanding, Alexion is providing guidance of $2.82 to $2.92 for non-GAAP earnings per share for the year. The Company's GAAP effective tax rate is expected to be in the range of 29 to 31 percent. The Company's share-based compensation expense for the year is expected to be in a range of $63 to $67 million.

Conference Call/Web Cast Information:

Alexion will host a conference call/webcast to discuss matters mentioned in this release. The call is scheduled for today, February 14, at 10:00 a.m., Eastern Time. To participate in this conference call, dial 888-206-4836 (USA) or 913-312-1267 (International), passcode 5044697 shortly before 10:00 a.m. ET. A replay of the call will be available from 1:00 p.m. ET through a limited time thereafter. The replay number is 888-203-1112 (USA) or 719-457-0820 (International), passcode 5044697. The audio webcast can be accessed at www.alexionpharma.com.

About Soliris:

Soliris is a first-in-class terminal complement inhibitor developed from the laboratory through regulatory approval and commercialization by Alexion. Soliris is approved in the US, European Union, Japan and other countries as the first and only treatment for patients with paroxysmal nocturnal hemoglobinuria (PNH), a debilitating, ultra-rare and life-threatening blood disorder, characterized by complement-mediated hemolysis (destruction of red blood cells). Soliris is indicated to reduce hemolysis. Soliris is also approved in the US and the European Union as the first and only treatment for patients with atypical hemolytic uremic syndrome (aHUS), a debilitating, ultra-rare and life-threatening genetic disorder characterized by complement-mediated thrombotic microangiopathy, or TMA (blood clots in small vessels). Soliris is indicated to inhibit complement-mediated TMA. The effectiveness of Soliris in aHUS is based on the effects on TMA and renal function. Prospective clinical trials in additional patients are ongoing to confirm the benefit of Soliris in patients with aHUS. Soliris is not indicated for the treatment of patients with Shiga toxin *E. coli* related hemolytic uremic syndrome (STEC-HUS). For the breakthrough innovation in complement inhibition, Alexion and Soliris have received the pharmaceutical industry's highest honors: the 2008 Prix Galien USA Award for Best Biotechnology Product with broad implications for future biomedical research and the 2009 Prix Galien France Award in the category of Drugs for Rare Diseases. More information including the full prescribing information on Soliris is available at www.soliris.net.

About Alexion:

Alexion Pharmaceuticals, Inc. is a biopharmaceutical company focused on serving patients with severe and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Alexion is the global leader in complement inhibition and has developed and markets Soliris® (eculizumab) as a treatment for patients with PNH and aHUS, two debilitating, ultra-rare and life-threatening disorders caused by chronic uncontrolled complement activation. Soliris is currently approved in more than 40 countries for the treatment of PNH, and in the United States and European Union for the treatment of aHUS. Alexion is evaluating other potential indications for Soliris and is developing four other highly innovative biotechnology product candidates, which are being investigated across nine severe and ultra-rare disorders beyond PNH and aHUS. This press release and further information about Alexion Pharmaceuticals, Inc. can be found at: www.alexionpharma.com.

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This news release contains forward-looking statements, including statements related to guidance regarding anticipated financial results for 2013, assessment of the Company's financial position and commercialization efforts, medical benefits and commercial

potential for Soliris for PNH and aHUS and other potential indications, expansion of clinical and commercial operations to additional countries, medical and commercial potential of Alexion's complement-inhibition technology and other technologies, plans for clinical programs for each of our product candidates and progress in developing commercial infrastructure. Forward-looking statements are subject to factors that may cause Alexion's results and plans to differ from those expected, including for example, decisions of regulatory authorities regarding marketing approval or material limitations on the marketing of Soliris for PNH and aHUS and other potential indications, delays in arranging satisfactory manufacturing capabilities and establishing commercial infrastructure, the possibility that results of clinical trials are not predictive of safety and efficacy results of Soliris in broader patient populations in the disease studied or other diseases, the risk that acquisitions will not result in short-term or long-term benefits, the possibility that current results of commercialization are not predictive of future rates of adoption of Soliris in PNH, aHUS or other diseases, the risk that third parties will not agree to license any necessary intellectual property to Alexion on reasonable terms or at all, the risk that third party payors (including governmental agencies) will not reimburse or continue to reimburse for the use of Soliris at acceptable rates or at all, the risk that estimates regarding the number of patients with PNH, aHUS or other disorders are inaccurate, and a variety of other risks set forth from time to time in Alexion's filings with the US Securities and Exchange Commission, including but not limited to the risks discussed in Alexion's Quarterly Report on Form 10-Q for the three and nine-month periods ended September 30, 2012 and in our other filings with the US Securities and Exchange Commission. Alexion does not intend to update any of these forward-looking statements to reflect events or circumstances after the date hereof, except when a duty arises under law.

In addition to financial information prepared in accordance with GAAP, this news release also contains non-GAAP financial measures that we believe, when considered together with the GAAP information, provide investors and management with supplemental information relating to performance, trends and prospects that promote a more complete understanding of our operating results and financial position during different periods. These non-GAAP financial measures are not intended to be considered in isolation or as a substitute for, or superior to, the financial measures prepared and presented in accordance with GAAP and should be reviewed in conjunction with the relevant GAAP financial measures. Please refer to the attached Reconciliation of GAAP to Non-GAAP Net Income for explanations of the amounts adjusted to arrive at non-GAAP net income and non-GAAP earnings per share amounts for the three and twelve month periods ended December 31, 2012 and 2011.

(Tables Follow)

ALEXION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)
(unaudited)

	Three months ended December 31		Twelve months ended December 31	
	2012	2011	2012	2011
Net product sales	$320,526	$227,559	$1,134,114	$783,431
Cost of sales	33,147	28,798	126,214	93,140
Gain on intellectual property settlement	-	-	(53,377)	-
Total cost of sales	33,147	28,798	72,837	93,140
Research and development	63,409	34,398	222,732	137,421
Selling, general and administrative	112,624	86,567	384,678	308,176
Impairment of intangible asset	-	-	26,300	-
Acquisition-related costs	3,365	2,322	22,812	13,486
Amortization of purchased intangible assets	105	104	417	382
Total operating expenses	179,503	123,391	656,939	459,465
Operating income	107,876	75,370	404,338	230,826
Interest and other expense	606	1,292	6,772	1,158
Income before income taxes	107,270	74,078	397,566	229,668
Income tax provision	26,298	25,908	142,744	54,353

Net income	$ 80,972	$ 48,170	$ 254,822	$175,315
Earnings per common share				
Basic	$ 0.42	$ 0.26	$ 1.34	$ 0.96
Diluted	$ 0.40	$ 0.25	$ 1.28	$ 0.91
Shares used in computing earnings per common share				
Basic	194,141	184,452	190,461	183,220
Diluted	201,061	193,370	198,501	191,806

ALEXION PHARMACEUTICALS, INC.
RECONCILIATION OF GAAP TO NON-GAAP NET INCOME
(in thousands, except per share amounts)
(unaudited)

	Three months ended December 31		Twelve months ended December 31	
	2012	2011	2012	2011
GAAP net income	$ 80,972	$ 48,170	$ 254,822	$ 175,315
Share-based compensation expense (1)	13,691	10,337	54,013	44,763
Acquisition-related costs (2)	3,365	2,322	22,812	13,486
Amortization of purchased intangible assets	105	104	417	382
Non-cash taxes (3)	24,158	19,547	98,364	32,155
Tax related to acquisition structuring (4)	-	-	21,812	-
Gain on intellectual property settlement (5)	-	-	(53,377)	-
Impairment of intangible asset (6)	-	-	26,300	-
Non-GAAP net income	$ 122,291	$ 80,480	$ 425,163	$ 266,101
Shares used in computing diluted earnings per share (GAAP)	201,061	193,370	198,501	191,806
Shares used in computing diluted earnings per share (non-GAAP)	202,249	194,732	199,787	193,539
GAAP earnings per share - diluted	$ 0.40	$ 0.25	$ 1.28	$ 0.91
Non-GAAP earnings per share - diluted	$ 0.60	$ 0.41	$ 2.13	$ 1.38

(1) The following table summarizes the share-based compensation expense for each expense category in our condensed consolidated statements of operations:

	Three months ended December 31		Twelve months ended December 31	
	2012	2011	2012	2011
Share-based compensation expense:				
Cost of sales	$ 876	$ 613	$ 2,815	$ 2,375
Research and development	3,466	2,270	13,839	9,759
Selling, general and administrative	9,349	7,454	37,359	32,629
	$ 13,691	$ 10,337	$ 54,013	$ 44,763

(2) The following table summarizes acquisition-related costs:

	Three months ended December 31		Twelve months ended December 31	
	2012	2011	2012	2011
Acquisition-related costs:				
Separately-identifiable employee costs	$ 117	$ -	$ 3,669	$ 6,597
Professional fees	1,031	2,039	12,593	5,489
Changes in fair value of contingent consideration	2,217	283	6,550	1,400
	$ 3,365	$ 2,322	$ 22,812	$ 13,486

(3) Non-cash taxes represents the adjustment from GAAP tax expense to the amount of taxes that are payable in cash. The adjustment includes tax amounts that are not currently payable in cash due to the continued utilization of our US net operating losses and credits.

In the third quarter of 2011, we elected to claim foreign tax and orphan drug credits resulting in a tax benefit of $16,300. The non-cash tax adjustment for the twelve months ended December 31, 2011 include these tax benefits which were recognized in the GAAP tax provision and were not received in cash.

(4) The tax provision for the twelve months ended December 31, 2012 includes tax expense of $21,812 related to the structuring of the Enobia acquisition.

(5) In October 2012, we entered into a settlement and license agreement which included an upfront payment. The Company recognized a gain of $53,377 in cost of sales during the three months ended September 30, 2012, which was the result of a reversal of a portion of the accrued liability, net of the effect of the upfront payment.

(6) During the three months ended September 30, 2012, we recorded an impairment of an acquired in-process research and development asset of $26,300 related to a preclinical AMD program.

ALEXION PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	December 31 2012	December 31, 2011
Cash and cash equivalents	$ 989,501	$ 540,865
Trade accounts receivable, net	295,598	244,288
Inventories, net	94,521	81,386
Deferred tax assets, current	26,086	19,132
Other current assets	89,894	55,599
Property, plant and equipment, net	165,629	165,852
Deferred tax assets, noncurrent	13,954	103,868
Intangible assets, net	646,678	91,604
Goodwill	253,645	79,639
Other noncurrent assets	38,054	12,518
Total assets	$ 2,613,560	$ 1,394,751
Accounts payable and accrued expenses	$ 271,275	$ 199,653
Current portion of long-term debt	48,000	-
Other current liabilities	40,814	28,132
Long-term debt	101,000	-
Contingent consideration	139,002	18,120
Other noncurrent liabilities	42,619	14,354
Total liabilities	642,710	260,259
Total stockholders' equity	1,970,850	1,134,492
Total liabilities and stockholders' equity	$ 2,613,560	$ 1,394,751

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Source: Alexion Pharmaceuticals, Inc.